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Dkt. 49034-AA-PCT-US/JPW/AJM/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ira Tabas et al.
Serial No. : 10/646,412
Filing Date : August 22, 2003.
For : METHOD FOR TREATING A SUBJECT SUFFERING FROM
CONDITIONS ASSOCIATED WITH AN EXTRACELLULAR
ZINC SPHINGOMYELINASE

1185 Avenue of the Americas
New York, New York 10036
November 24, 2003

Mail Stop: 16

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL OF VERIFIED STATEMENTS
(DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER
37 C.F.R. §1.9(f) AND §1.27(d) AND REQUEST FOR REFUND**

A filing fee of \$926.00 was originally paid in connection with the filing of the above-identified patent application on August 22, 2003. The corresponding fee for a small entity is \$463.00. The deadline for making a request for refund is three months after the August 22, 2003 filing date, i.e. November 22, 2003. Since November 22, 2003 falls on a Saturday, a response filed on the next succeeding day which is not a Saturday, Sunday or Federal holiday, i.e. Monday, November 24, 2003, is considered timely under 37 C.F.R. §1.7. Accordingly, this Transmittal is being timely filed. All rights in the United States under this application are either assigned or licensed to a small entity and this request is being timely made. A refund in the amount of \$463.00 is hereby requested pursuant to 37 C.F.R. §1.28(a) and §1.26. This refund should be credited to Deposit Account No. 03-3125 under Docket No. 49034-AA-PCT-US.

Applicants: Ira Tabas et al.
Serial No: 10/646,412
Filed: August 22, 2003
Page 2

In support of this request for a refund, applicants submit herewith the following: (1) a Verified Statement (Declaration) Claiming Small Entity Status Under 37 C.F.R. §1.9(f) and §1.27(d) (Non-Profit Organization) signed by Michael J. Cleare, Ph.D. for The Trustees of Columbia University in the City of New York (**Exhibit A**); and (2) a Verified Statement (Declaration) Claiming Small Entity Status Under 37 C.F.R. §1.9(f) and §1.27(d) (Non-Profit Organization) signed by Steven E. McKenzie, M.D., Ph.D. for Thomas Jefferson University (**Exhibit B**). The Statements are signed by the authorized officials of the entities who have rights in the subject application, namely The Trustees of Columbia University in the City of New York and Thomas Jefferson University.

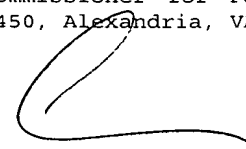
No fee is deemed necessary in connection with the filing of this Transmittal. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: 16, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Alan J. Morrison
Reg. No. 37,399

11/24/03
Date

Applicant or Patentee: Ira Tabas et al.

Attorney's 0575/49034-AA-
Docket No: PCT-US/JPW/AJM/
MVM

Serial or Patent No.: 10/646,412

Filed or Issued: August 18, 2003

Title of Invention or Patent: METHOD FOR TREATING A SUBJECT SUFFERING FROM CONDITIONS ASSOCIATED WITH AN EXTRACELLULAR ZINC SPHINGOMYELINASE



VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: The Trustees of Columbia University in the City of New York

Address of Organization: Broadway and West 116th Street
New York, NY 10027

TYPE OF ORGANIZATION:

☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3)
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
NAME OF STATE: _____
CITATION OF STATUTE: _____
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
NAME OF STATE: _____
CITATION OF STATUTE: _____

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. §1.9(e)* for purposes of paying reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to the invention entitled

METHOD FOR TREATING A SUBJECT SUFFERING FROM CONDITIONS ASSOCIATED WITH AN EXTRACELLULAR ZINC SPHINGOMYELINASE
by inventor(s) Ira Tabas, Scott L. Schissel and Kevin Jon Williams

described in:

☒ the specification filed herewith
☒ application serial no. 10/646,412 filed August 18, 2003
☐ patent no. _____ issued _____

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive each individual, concern, or organization known to have rights to the invention is listed below^a and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d)* or a nonprofit organization under 37 C.F.R. 1.9(e)*

^a NOTE: Separate verified statements are required from each person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

Name: Thomas Jefferson University

Address: 11th & Walnut Streets

Philadelphia, PA 19107

☐ Individual ☐ Small Business Concern ☒ Nonprofit Organization

37 C.F.R. §§1.9(d), 1.9(e)

(d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published on September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:

§121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.

(a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

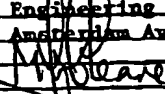
(b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.

(e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Nonprofit
Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Michael J. Cleary, Ph.D.
Title In Organization: Executive Director - Columbia Innovation Enterprise
Address: Columbia University - Engineering Terrace, Suite 363
West 120th Street and Amsterdam Avenue, New York, NY 10027
Signature: 
Date Of Signature: 11/18/08

37 C.F.R. §1.28(b)

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to §1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to §1.34(a) of this part.

Applicant or Patentee: Ira Tabas et al. Attorney's 0575/49034-AA-
Serial or Patent No.: 10/646,412 Docket No: PCT-US/JPW/AJM/
Filed or Issued: August 18, 2003 MVM
Title of Invention or Patent: METHOD FOR TREATING A SUBJECT SUFFERING FROM CONDITIONS
ASSOCIATED WITH AN EXTRACELLULAR ZINC SPHINGOMYELINASE



VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: Thomas Jefferson University

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TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and
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☒ the specification filed herewith
☒ application serial no. 10/646,412 filed August 18, 2003
☐ patent no. _____ issued _____

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Small Entity/Nonprofit
Page -2-

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Steven E. McKenzie, M.D., Ph.D.
Title In Organization: Vice President for Technical Transfer and Science Policy
Address: Office of Technology Transfer, 1020 Locust Street, Suite M34
Philadelphia, PA 19107 Thomas Jefferson University
Signature: Steven E. McKenzie, M.D., Ph.D.
Date Of Signature: November 18, 2007

37 C.F.R. §1.28(b)

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